

**AP7 Rec'd PCT/PTO 07 APR 2006**

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL LETTER TO THE UNITED STATES</b> <b>DESIGNATED/ELECTED OFFICE (DO/EO/US)</b> <b>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>2177.046</b> U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/575062</b>
INTERNATIONAL APPLICATION NO. <b>PCT/IB2004/003210</b>	INTERNATIONAL FILING DATE <b>September 30, 2004</b>	PRIORITY DATE <b>October 7, 2003</b>
TITLE OF INVENTION <b>AMINO-ACID COMPOSITIONS FOR THE TREATMENT OF PATHOLOGICAL CONDITIONS DISTINGUISHED BY INSUFFICIENT MITOCHONDRIAL FUNCTION</b>		
APPLICANT(S) FOR DO/EO/US <b>DIOGUARDI, Francesco Saverio</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C.             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> </ol> <p><b>Items 11 to 20 below concern document(s) or information</b></p> <ol style="list-style-type: none"> <li>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A preliminary amendment.</li> <li>14. <input checked="" type="checkbox"/> An application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).</li> </ol>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<b>U.S. APPLICATION NO.</b> (if known, see 37 CFR 1.5) 307575002 Unknown	<b>INTERNATIONAL APPLICATION NO.</b> PCT/IB2004/003210	<b>ATTORNEY'S DOCKET NUMBER</b> 2177.046
20. <input checked="" type="checkbox"/> Other items or information:		
The following fees are submitted:		<b>CALCULATIONS</b>
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))		\$ 300.00
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200		\$ 200.00
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500		\$ 400.00
<b>TOTAL OF 21, 22 and 23 =</b>		\$ 900.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	RATE
19 - 100 =	0 /50 =	0 x \$250.00
		\$ 0.00
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	22 - 20 =	2 x \$50.00
Independent	2 - 3 =	0 x \$200.00
Multiple Dependent Claims (if applicable) <input type="checkbox"/>		+ \$360.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>		\$ 1,000.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$ 0.00
<b>SUBTOTAL =</b>		\$ 1,000.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		+ \$
<b>TOTAL NATIONAL FEE =</b>		\$ 1,000.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per		+ \$
<b>TOTAL FEES ENCLOSED =</b>		\$ 1,000.00
		Amount to be refunded: \$
		Amount to be charged: \$

10/575062

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- APR 20 2006 PTO 07 APR 2006
- a. ☒ A check in the amount of \$1,000.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account \_\_\_\_\_ in the amount of \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 08-1935. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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Dated: April 7, 2006

  
SIGNATURE

Kathy Smith Dias

NAME

41,707

REGISTRATION NUMBER

10/575002

AP20060407 APR 2006

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

Applicant: DIOGUARDI, Francesco Saverio

Title: AMINO-ACID COMPOSITIONS FOR THE TREATMENT OF PATHOLOGICAL  
CONDITIONS DISTINGUISHED BY INSUFFICIENT MITOCHONDRIAL  
FUNCTION

Attorney Docket No.: 2177.046

"EXPRESS MAIL" Mailing Label No.: EV 793606032 US

Date of Deposit: April 7, 2006

Enclosed are:

- Express Mail Certificate - Label No.: EV 793606032 US
- One (1) Return Receipt Postcard
- Check in the amount of \$1,000.00 (Filing Fee) (Large Entity)
- Transmittal Letter under 35 U.S.C. 371 (3 pps)
- Copy of International Application as filed (19 pages)
- Executed Declaration and Power of Attorney
- Preliminary Amendment (8 pages) and an Abstract of the Disclosure (one page)
- Application Data Sheet (2 pages)
- Copy of the International Search Report
- Information Disclosure Citation and copies of cited references

37 CFR 1.10 Certification

I hereby certify that this paper and the indicated enclosures are being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and addressed to:

MAIL STOP PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DARLENE E. NOVAL  
(Typed or printed name of person mailing paper or fee)

Darlene E. Noval  
(Signature of person mailing paper or fee)